DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED

November 18, 1996

cc: HFI-35/FOI Sta
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-12

Ken L. Respotnik
Owner
Organico Institute Corporation
Route 1, Box 335A
Ashland, Wisconsin 54806

Dear Mr. Respotnik:

An inspection of Organico Institute Corporation, Ashland, WI, by FDA Investigator Kathy A. Girolamo on October 7-8, 1996, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for acidified food manufacturers [Title 21, Code of Federal Regulations (CFR), Parts 113 and 114]. Such conditions cause the food products being manufactured at this facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

Objectionable conditions found during the current inspection were cited on a form FDA-483, Inspectional Observations. They were discussed with you at the close of the investigation.

Specifically, our investigator found:

1. The meter used for determining pH of finished product that is above 4.0 does not have the required accuracy (±0.1 unit).

2. Your processing records do not include all the following items per 21 CFR 114.100:

   A. Documentation of the pH values for all batches of acidified and potentially acidified foods.

   B. Documentation that the packaging and raw material has been examined prior to use. Documentation that the container integrity is checked for leakage prior to shipping.

   C. Documentation that all acidified and potentially acidified food processing records are reviewed.

3. Your firm fails to maintain a Deviation File as required in 21 CFR 113.89 and 114.100(c). Cook time deviations were noted during record review without deviations filed and reviewed.

We would encourage you to review the manufacturing processes on all your products to ensure that processes have been filed for all potentially acidified foods manufactured at your firm.

During the inspection the investigator collected a sample of Carrot and a Cucumber relish (sample no. 97-079-002). Analysis of the product found a 25mm cat or dog hair and a dog hair fragment measuring 16mm in length. It is your responsibility to review your operations, isolate possible sources from which the hair may have entered into the product, and take corrective action to prevent a recurrence of these findings. Filth in your finished product causes it to be adulterated under Section 402(a)(3) of the Federal Food, Drug and Cosmetic Act. Food that is found to be adulterated is subject to regulatory action.

This letter is not meant to be an all-inclusive listing of the deficient conditions and practices at your food facility. As owner, the most responsible individual at Organico Institute Corp., it is ultimately your responsibility to ensure that the relish/salsa manufacturing operation in Ashland, WI, is operating in compliance with the Federal Food, Drug and Cosmetic Act and all associated regulations.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing within 15 working days of your receipt of this letter of the measures you intend to take to correct the cited violations. If the corrections cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead, (612) 334-4100 ext. 156.

Sincerely yours,

John Feldman
Director
Minneapolis District

HEM/ccl